

Application Serial No. 10/669,490
Filed September 24, 2003
Applicant Gilbert R. Gonzales et al.
Request for Continued Examination dated December 19, 2007
Confirmation No. 3979
Attorney Docket No. GONZ-07

Listing of Claims

1. (Presently Amended) A pharmaceutical composition comprising ~~a non-sedative, an~~ analgesic dosage formulation effective to treat acute pain and avoid a sedative effect, the dosage formulation including an oral dissolution agent, a buffer and methadone, said buffer effective to buffer the composition to a pH of at least about 6 during absorption of the methadone through the oral mucosa.
2. (Original) The composition of claim 1 wherein the composition is buffered to a pH in the range from about 7 to about 10 during absorption of the methadone through the oral mucosa.
3. (Original) The composition of claim 1 wherein the buffer is selected from the group consisting of a phosphate buffer, a glycylglycine buffer, a carbonate buffer, a bicarbonate buffer, a tris buffer, a tartrate buffer, a borate buffer, an acetate buffer, a maleate buffer and combinations thereof.
4. (Original) The composition of claim 1 in a solid formulation selected from a lozenge, a lollipop, a troche, a dragée, a chewable gum, a solid candy, a granular solid, a chewable tablet, an orally dispersable tablet, an orally dissolvable tablet, an orally dissolvable pill and an orally dissolvable capsule.

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5. (Withdrawn) The composition of claim 1 in a liquid formulation selected from a solution, a suspension, a paste and an emulsion.
6. (Original) The composition of claim 1 containing at least about 0.5 mg of methadone per dose.
7. (Original) The composition of claim 1 containing methadone in a weight range from about 2 mg to about 50 mg per dose.
8. (Original) The composition of claim 1 wherein the oral dissolution agent is selected from the group consisting of acacia, alginic acid, carbomer, carboxymethylcellulose, calcium, carboxymethylcellulose sodium, microcrystalline cellulose, dextrans, dextrin, dextrose, methyl cellulose, ethyl cellulose, fructose, gelatin, guar gum, hydroxyethyl cellulose, hydroxypropyl cellulose, hydroxypropyl methylcellulose, lactitol, lactose, lecithin, maltodextrine, mannitol, poloxamer, polyethylene glycol, polymethacrylates, poly oxyethylene alkyl ethers, polyvinyl alcohol, propylene glycol alginate, sodium alginate, sodium ascorbate, sodium starch glycolate, sodium saccharin, sorbitol, starch, pregelatinized starch, sucrose, tragacanth, trimethylglycine, xanthan gum, xylitol, zein, and combinations thereof.

9. (Presently Amended) A pharmaceutical composition comprising ~~a non-sedative~~, an analgesic dosage formulation effective to treat acute pain and avoid a sedative effect, the dosage formulation including an oral dissolution agent, a buffer, and at least about 0.5 mg methadone, the buffer effective to buffer the composition to a pH in the range from about 7 to about 10 during absorption of methadone through the oral mucosa.

10. (Original) The composition of claim 9 wherein the composition is buffered to a pH in the range from about 8 to about 9 during absorption of methadone through the oral mucosa.

11. (Original) The composition of claim 9 wherein the buffer is selected from the group consisting of a phosphate buffer, a glycylglycine buffer, a carbonate buffer, a bicarbonate buffer, a tris buffer, a tartrate buffer, a borate buffer, an acetate buffer, a maleate buffer and combinations thereof.

12. (Original) The composition of claim 9 in a solid formulation selected from the group consisting of a lozenge, a lollipop, a troche, a dragée, a chewable gum, a solid candy, a granular solid, a chewable tablet, an orally dispersable tablet, an orally dissolvable tablet, an orally dissolvable pill and an orally dissolvable capsule.

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13. (Original) The composition of claim 9 containing methadone in a weight range from about 2 mg to about 50 mg per dose.

14. (Original) The composition of claim 9 wherein the formulation is one of a lollipop and a lozenge and contains methadone in a weight range from about 2 mg to about 10 mg per dose.

15. (Original) The composition of claim 9 wherein the oral dissolution agent is selected from the group consisting of acacia, alginic acid, carbomer, carboxymethylcellulose, calcium, carboxymethylcellulose sodium, microcrystalline cellulose, dextrans, dextrin, dextrose, methyl cellulose, ethyl cellulose, fructose, gelatin, guar gum, hydroxyethyl cellulose, hydroxypropyl cellulose, hydroxypropyl methylcellulose, lactitol, lactose, lecithin, maltodextrine, mannitol, poloxamer, polyethylene glycol, polymethacrylates, poly oxyethylene alkyl ethers, polyvinyl alcohol, propylene glycol alginate, sodium alginate, sodium ascorbate, sodium starch glycolate, sodium saccharin, sorbitol, starch, pregelatinized starch, sucrose, tragacanth, trimethylglycine, xanthan gum, xylitol, zein, and combinations thereof.

16. (Presently Amended) A pharmaceutical composition comprising methadone and an oral dissolution agent in ~~a non-sedative~~, an analgesic dosage formulation effective to treat acute pain and avoid a sedative effect, the dosage formulation selected from one of a lollipop and a lozenge for oral administration of the methadone.

17. (Original) The composition of claim 16 further comprising a pH buffer in an amount sufficient to provide a pH in the range from about 6 to about 10 in the oral cavity.

18. (Original) The composition of claim 16 further comprising a pH buffer in an amount sufficient to provide a pH in the range from about 8 to about 9 in the oral cavity.

19. (Original) The composition of claim 17 wherein the pH buffer is selected from the group consisting of a phosphate buffer, a glycylglycine buffer, a carbonate buffer, a bicarbonate buffer, a tris buffer, a tartrate buffer, a borate buffer, an acetate buffer, a maleate buffer and combinations thereof.

20. (Original) The composition of claim 16 wherein the an oral dissolution agent is selected from the group consisting of acacia, alginic acid, carbomer, carboxymethylcellulose, calcium, carboxymethylcellulose sodium, microcrystalline cellulose, dextrans, dextrin, dextrose, methyl cellulose, ethyl cellulose, fructose, gelatin,

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guar gum, hydroxyethyl cellulose, hydroxypropyl cellulose, hydroxypropyl methylcellulose, lactitol, lactose, lecithin, maltodextrine, mannitol, poloxamer, polyethylene glycol, polymethacrylates, poly oxyethylene alkyl ethers, polyvinyl alcohol, propylene glycol alginate, sodium alginate, sodium ascorbate, sodium starch glyolate, sodium saccharin, sorbitol, starch, pregelatinized starch, sucrose, tragacanth, trimethylglycine, xanthan gum, xylitol, zein, and combinations thereof.

21. (Original) The composition of claim 16 containing at least about 0.5 mg of methadone per dose.

22. (Original) The composition of claim 16 containing methadone in a weight range from about 2 mg to about 10 mg per dose.

23. (Withdrawn) A method of transmucosally administering methadone to a patient, the method comprising:

providing to the patient a pharmaceutical composition comprising an orally dissolvable solid dosage formulation including methadone and a buffer effective to buffer the oral cavity to a pH of at least about 6 for oral transmucosal absorption of a therapeutically effective amount of the methadone; and

instructing the patient to orally dissolve the composition to transmucosally administer the methadone to the patient.

24. (Withdrawn) The method of claim 23 further comprising delivering the methadone to the blood circulation of the patient by absorption through the oral mucosal tissue.

25. (Withdrawn) The method of claim 23 wherein the patient is provided one of a solid formulation selected from a lozenge, a lollipop, a troche, a dragée, a chewable gum, a solid candy, a granular solid, a chewable tablet, an orally dispersable tablet, an orally dissolvable tablet, an orally dissolvable pill and an orally dissolvable capsule, and a liquid formulation selected from a solution, a suspension, and an emulsion.

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26. (Withdrawn) The method of claim 23 wherein the methadone is administered to treat pain.

27. (Withdrawn) The method of claim 23 wherein the methadone is administered to provide at least one of an analgesic effect, a sedative effect, a euphoric effect, an antitussive effect, an NMDA antagonistic effect, an opioid substitute for reducing opioid-induced constipation, and a reduction of at least one of catecholamine uptake, norepinephrine re-uptake and serotonin re-uptake, in the patient's body.

28. (Withdrawn) The method of claim 23 wherein the methadone is administered to treat drug addiction, opioid tolerance, pathological itching, seizure, and a combination thereof.

29. (Withdrawn) A method of treating pain in a patient, the method comprising:

administering to the patient a pharmaceutical composition comprising an orally dissolvable solid dosage formulation including methadone and a buffer effective to buffer the oral cavity to a pH of at least about 6 for oral transmucosal absorption of a therapeutically effective amount of the methadone; and

delivering the methadone to the oral mucosal tissue for transmucosal absorption into the blood circulation to treat pain in the patient.

30. (Withdrawn) The method of claim 29 further comprising treating the patient for drug addiction, opioid tolerance, pathological itching, seizure, a sedative effect, a euphoric effect, an antitussive effect, an NMDA antagonistic effect, an opioid substitute for reducing opioid-induced constipation, and a reduction of at least one of catacholamine uptake, norepinephrine re-uptake and serotonin re-uptake, and a combination thereof in the patient's body.

31. (Withdrawn) The method of claim 29 wherein the pain is attributed to one of cancer pain, neuropathic pain, chronic pain, acute pain, somatic pain, autonomic nervous system mediated pain, central pain, post-herpetic neuralgic pain, and combinations thereof.

32. (Withdrawn) The method of claim 29 wherein the formulation administered is one of a solid formulation selected from a lozenge, a lollipop, a troche, a dragée, a chewable gum, a solid candy, a granular solid, a chewable tablet, an orally dispersable tablet, an orally dissolvable tablet, an orally dissolvable pill and an orally dissolvable capsule, and a liquid formulation selected from a solution, a suspension, and an emulsion.

33. (Withdrawn) The method of claim 29 further comprising administering the composition as needed to treat the pain.

34. (Withdrawn) The method of claim 29 further comprising administering to the patient a second pharmaceutical composition comprising methadone in a formulation wherein the methadone is absorbed into the blood circulation in a substantially non-transmucosal route.

35. (Withdrawn) A method of treating pain in a patient, the method comprising:

administering to the patient a pharmaceutical composition comprising methadone and an oral dissolution agent in a dosage formulation selected from one of a lollipop and a lozenge for oral administration of the methadone to treat pain in the patient.

36. (Withdrawn) The method of claim 35 further comprising delivering the methadone in the oral cavity of the patient for oral transmucosal absorption of the methadone into blood circulation.

37. (Withdrawn) The method of claim 35 further comprising treating the patient for drug addiction, opioid tolerance, pathological itching, seizure, a sedative effect, a euphoric effect, an antitussive effect, an NMDA antagonistic effect, an opioid substitute for reducing opioid induced constipation, and a reduction of at least one of catacholamine uptake, norepinephrine re-uptake and serotonin re-uptake, and a combination thereof in the patient's body.

38. (Withdrawn) The method of claim 35 wherein the pain is attributed to one of cancer pain, neuropathic pain, chronic pain, acute pain, somatic pain, autonomic nervous system mediated pain, central pain, post-herpetic neuralgic pain, and combinations thereof.

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39. (Withdrawn) The method of claim 35 further comprising administering the composition as needed to treat the pain.

40. (Withdrawn) The method of claim 35 further comprising administering to the patient a second pharmaceutical composition comprising methadone in a formulation wherein the methadone is absorbed into the blood circulation in a substantially non-transmucosal route.